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10/560,647	05/24/2006	Richard J Stenton	355493-2975	3822
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EXAMINER				
HAND, MELANIE JO				
ART UNIT		PAPER NUMBER		
3761				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,647

Applicant(s)

STENTON, RICHARD J

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. It is noted that this action is non-final because the rejections of claim 11 was intended to be under 35 U.S.C. 103 in the previous action and claim 12 is now rejected under new grounds over Emerit in view of Jonn. The new grounds of rejection of claims 11 and 12 in this action are not prompted by the amendment to the claims.
2. Examiner acknowledges the telephonic restriction requirement and withdraws claim 18 from consideration in this Office action, however the amendment to the claims renders the requirement moot. It is examiner's position that, were the claims as amended presented originally, they would not have prompted a restriction requirement because the product cannot be used in a materially different method from that which is claimed, nor can the method be practiced with a materially different product than that which is claimed.
3. Applicant's arguments with respect to claims 10 and 12-18 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims. However, examiner will briefly address the essence of applicant's arguments herein. As to arguments regarding the rejections under 35 U.S.C. 102, the tab 24 is integral with the rest of the reservoir 16 which is in turn integral with the maintaining means 14. (Page 2, ¶13)
Maintaining means 14 has a portion that extends below the pad 30 that is necessarily gripped when the pad is gripped to break the breakable connection, i.e. nipple 26. Thus, Emerit discloses that the tab 24, integral with maintaining means 14, has a handle portion external to pad 30 such that when the breakable connection 26 is severed, the tab can be and is readily separated from the dispenser as that limitation is understood from and supported by applicant's specification, i.e. that the tab is separated insofar as to allow fluid to pass into the pad but is not

entirely physically separated from the dispenser. As to applicant's argument that Emerit teaches away from the claimed applicator, all of the limitations of the claimed device are either anticipated by or suggested by Emerit, alone or in combination with Jonn. Perceived disadvantages are not sufficient to constitute a teaching away from the claimed invention by a reference. There is no breakage of the breakable connection of Emerit meeting the claim limitations that would disrupt or compromise the function of the device because the claims only recite bending or breaking the breakable connection, which the connection of Emerit is specifically designed to withstand. The rejection of claims 13-15 is over the combination of Emerit and Jonn, thus applicant must argue the combination, rather than simply the Emerit reference. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Emerit (WO 00/71198 A-English translation).

With respect to **claim 10**: Emerit discloses an applicator 10 comprising a reservoir in the form of liquid storage cartridge 16 adapted to contain a fluid. A pad 30 formed by folding absorbent

pledget 12 is in fluid communication with the reservoir 16 via neck 20 of the body 18 of cartridge 16. (Page 2, ¶¶2-6) A tab in the form of stopper 24 which is integral with maintaining means 14 which is in turn integral with the cartridge 16 serves to seal the fluid reservoir at a breakable connection, namely nipple 26. The tab 24, being integral with maintaining means 14, has a handle external to the pad 30 as seen in Fig. 1 or Fig. 3 as the portion of the maintaining means 14 that extends below the pad 30. The breakable connection 26 is internal to the pad 30 inasmuch as it is surrounded by the material of pad 30, as can also be seen in Figs. 1 and 3. The reservoir 16 comprises a wall which is adapted to flex sufficiently under pressure from an operator's finger to force fluid from the reservoir 16 into the pad 30. (Page 3, ¶10) The tab 24 includes a stem in the form of neck 20 attached to the applicator at the breakable connection 26. The pad 30 includes a channel for slidably receiving the stem formed by folding the pad 30. The tab stem 20 passes through the pad 30, and the breakable connection is formed of friable material such that the bending of the tab 24 relative to the applicator 10 as a result of bending handle 14 when gripping the pad 30 causes breaking of the breakable connection 26 to allow passage of fluid from the reservoir 16 into the pad 10, necessarily causing separation of the tab 24 connected to the breaking connection 26 from the applicator. (Page 3, ¶¶6,12)

With respect to **claim 16**: The tab handle portion of maintaining means 14 integral with tab 24 has a twist-off portion that facilitates breakage of the tab 24 at the breakable connection 26 inasmuch as the action of grabbing the pad 30 necessarily involves grabbing the entire maintaining means 14, including the handle portion that protrudes below the pad 30 in Fig. 1, and bending/twisting the handle portion to break the connection 26. (Fig. 1)

With respect to **claim 17**: Emerit discloses a method for applying a fluid onto mammalian skin.

With regard to step a), the method comprises selecting an applicator 10 comprising a reservoir 16 adapted to contain the fluid, a pad 30 in fluid communication with the reservoir 16 via neck 20, and a tab 24 serving to seal the fluid reservoir at a breakable connection, i.e. nipple 26, wherein breaking of the breakable connection 26 allows passage of fluid from the reservoir 16 into the pad 30. The tab 24, being integral with maintaining means 14, has a handle external to the pad 30 as seen in Fig. 1 or Fig. 3 as the portion of the maintaining means 14 that extends below the pad 30. The breakable connection 26 is internal to the pad 30 inasmuch as it is surrounded by the material of pad 30, as can also be seen in Figs. 1 and 3. With regard to step b), the method comprises manipulating the tab by twisting said tab in an angular direction thereby breaking the seal formed by the tab 24 such that fluid in the reservoir 16 flows into the pad 30, which necessarily results in separating the tab 24 from the applicator such that the fluid in reservoir 16 flows into pad 30. With regard to step c), the method comprises the step of applying the fluid from the pad onto the skin, i.e. cutaneous treatment. (Page 2, ¶¶2-6, Page 3, ¶¶10-12)

With respect to **claim 18**: Emerit discloses a method for applying a fluid onto mammalian skin. With regard to step a), the method comprises selecting an applicator 10 comprising: a reservoir in the form of cartridge 16 itself comprising a wall which flexes under pressure from an operator's finger and being adapted to contain the fluid, a pad 30 in fluid communication with the reservoir 16, and a tab 24 serving to seal the fluid reservoir at a breakable connection 26, wherein breaking of the breakable connection 26 allows passage of fluid from the reservoir into the pad. The tab 24, being integral with maintaining means 14, has a handle external to the pad 30 as seen in Fig. 1 or Fig. 3 as the portion of the maintaining means 14 that extends below the pad 30. The breakable connection 26 is internal to the pad 30 inasmuch as it is surrounded by

the material of pad 30, as can also be seen in Figs. 1 and 3. With regard to step b), the method comprises manipulating the tab 24 by twisting it in an angular direction, thereby breaking the seal formed by the tab 24 and separating the tab 24 in a manner such that fluid in the reservoir 16 flows into the pad 30. With regard to step c), Emerit discloses that "the liquid is free to run out to soak the absorbent band (the pad), in particular under the action of manual pressure exerted on the flexible body of the cartridge". That is, Emerit discloses the step of applying finger pressure onto the flexible wall of the reservoir to cause it to flex sufficiently to force fluid from the reservoir into the pad. With regard to step d), Emerit discloses cutaneous treatment with the applicator via the fluid, i.e. applying the fluid from the pad 30 onto the skin. (Page 2, ¶¶2-6, Page 3, ¶¶10-12)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Emerit et al ('198-English translation).

With respect to **claim 11**: Emerit does not explicitly disclose that the channel in the pad 30 is oval in cross section. However, when one folds a square piece of material such as pledget 12 in half without creating a crease, a channel of oval cross-section is easily formed. Therefore, it would be obvious to one of ordinary skill in the art to modify the applicator of Emerit such that

the pledget 12 is folded such that the resulting pad 30 has a channel with an oval cross section with a reasonable expectation of success to easily accommodate the generally oval stem 20.

8. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emerit et al ('198) (English translation) in view of Jonn et al (U.S. Patent Application Publication No. 2002/0037310)

With respect to **claim 12**: Emerit discloses a medicinal substance as the fluid, but does not explicitly disclose that the fluid is a sterilizable fluid. Jonn discloses using an applicator to administer biocompatible adhesive to a tissue site to treat living tissue, which would therefore be considered a medicinal substance. The adhesive is necessarily sterilizable inasmuch as it is a cyanoacrylate ester adhesive, which is identical to the material disclosed by applicant for the claimed sterilizable tissue adhesive. Therefore, it would be obvious to one of ordinary skill in the art to use the applicator of Emerit to dispense a sterilizable fluid such as that taught by Jonn to treat living tissue. ('310, Abstract)

With respect to **claim 13**: Emerit discloses a medicinal substance as the fluid, but does not explicitly disclose that the fluid is a sterilizable tissue adhesive for surgical applications. Jonn discloses using an applicator to administer biocompatible adhesive to a tissue site to treat living tissue, which would therefore be considered a medicinal substance. The adhesive is sterilizable inasmuch as it is a cyanoacrylate ester adhesive, which is identical to the material disclosed by applicant for the claimed sterilizable tissue adhesive. Therefore, it would be obvious to one of ordinary skill in the art to use the applicator of Emerit to dispense a sterilizable tissue adhesive as taught by Jonn to treat living tissue. ('310, Abstract)

With respect to **claim 14**: Emerit does not disclose that the fluid is an adhesive. Jonn discloses an applicator dispensing a fluid that comprises a cyanoacrylate ester adhesive. The motivation to use the applicator of Emerit to dispense the adhesive, which is a sterilizable tissue adhesive as disclosed by applicant, is stated *supra* with respect to claim 13.

With respect to **claim 15**: Emerit does not disclose that the fluid is an adhesive. Jonn discloses an applicator dispensing a fluid that comprises butyl or octyl cyanoacrylate. ('310, ¶¶0044) The motivation to use the applicator of Emerit to dispense the adhesive, which is a sterilizable tissue adhesive as disclosed by applicant, is stated *supra* with respect to claim 13.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761